DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

> Group I, claim(s) 1-4, 11-36 and 50-52, drawn to a method of using a diagnostic marker(s) for diagnosing prostate cancer
>
> Group II, claim(s) 5-10, 37, drawn to a method of producing a medicament for the treatment of prostate cancer comprising at least one active substance which interacts with the protein annexin A3 and inhibits the activity and/or the abundance of the protein annexin A3.
>
> Group III, claim(s) 38-49, drawn to a method of using an active substance for the treatment of cancer.
>
> Group IV, claim(s) 36 and 53, drawn to a method for seeking active substances for the treatment of cancer.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1 is drawn to the use of annexin A3 as a diagnostic marker for prostate cancer. Schlegel et al. (US PgPub 20030108963) teach methods for detecting, diagnosing, preventing and treating human prostate cancer. Schlegel et al. disclose markers, including annexin A4, particularly useful in both screening for the presence of prostate cancer as well as for

assessing aggressiveness and metastatic potential of prostate cancer. Therefore, in view of Schlegel et al., the novel technical feature recited in Claim 1 is not special.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If any of groups I, III-IV is elected, Applicant must elect one from each of the following:

- Diagnostic Marker: (*note if Applicant elects more than 2 diagnostic markers Applicant must indicate which species are novel over the prior art).

  a.) annexin A3

  b.) annexin A1

  c.) annexin A2

  d.) annexin A5

  e.) mitochondrial enoyl-coenzyme A hydratase

  f.) PDI

  g.) SAP

  h.) nuclear chloride ion channel protein

  i.) HES1

  j.) proteasome alpha 2-subunit

  k.) protein adenine-phosphoribosyl-transferase

l.) inorganic pyrophophatase

m.) proteins listed in Claim 28 and 31

- Activity: (for each marker)

  a.) upregulated

  b.) downregulated

- Method of detection:

  a.) methods listed in claim 34

If Group II is elected Applicant must elect one from the following:

- Active substance: elect one from those listed in Claim 6-8

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The species listed are not novel in view of the teachings of Schlegel et al.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN
/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643